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(71) Applicant and
(72) Inventor: GLOSSOP, Neil, David [US/CA]; 49 Spadina Avenue #402c, Toronto, ON M5V2J1 (CA).

(74) Agents: ROONEY, Timothy, C. et al.; Pillsbury Winthrop Shaw Pittman LLP, P.O. Box 10500, McLean, VA 22102 (US).

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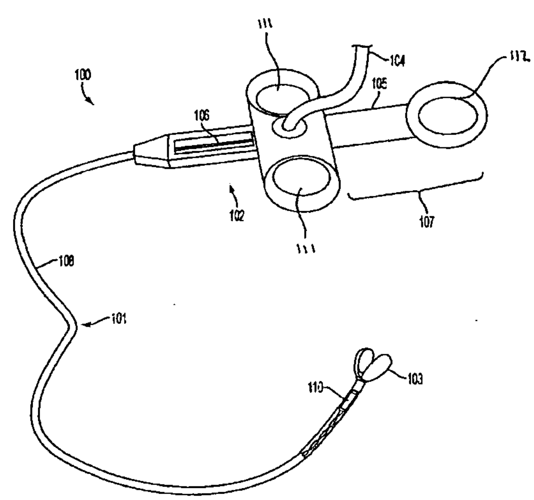

(57) Abstract: The invention provides an image-guided medical instrument that utilizes a tracking device to track the location of at least a portion of the instrument on at least one image of a patient's anatomy. The instrument may include a handle having an operating element, an elongated flexible body member connected to the handle, wherein the body member includes a lumen, a transmission element housed within the lumen of the body member, and a treatment apparatus connected to end of the transmission element, wherein actuation of the operating element actuates the treatment apparatus via the transmission element. The body member also includes at least one sensor element that is utilized by the tracking device to determine position information regarding the treatment apparatus that is used to display the location of the treatment apparatus on the at least one image of the patient's anatomy.

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System, Method and Apparatus for Navigated Therapy and Diagnosis

Related Applications

[001] This application claims priority to U.S. Provisional Application No. 60/692,272, filed June 21, 2005, which is hereby incorporated by reference herein in its entirety.

Field of the Invention

[002] The invention relates to a system, method and apparatus for navigated therapy and diagnosis.

Background of the Invention

[003] Access to natural and artificial passages in the body for treatment or investigation for possible treatment traditionally make use of elongated instruments that are inserted into the body. These instruments can be inserted into the body alone (e.g., as in a biopsy needle) or may make use of other implements such as an endoscope (e.g., a bronchoscope or colonoscope) through which the elongated instruments are inserted. Typical devices for access to natural or artificial passages in the body may include, for example, spring loaded biopsy "guns," endoscopic biopsy forceps, biopsy needles, polypectomy snares, cytology brushes, biliary guidewires, sphincterotomes, endoscopic retrograde cholangiography (ERCP) catheters, stone retrieval balloons, stents, lithotripsy baskets, graspers, baskets, rat-tooth and alligator forceps, sclerotherapy/injection needles, bipolar coagulation probes, dilation balloons, radiofrequency ablation devices, microwave ablation devices, cryotherapy probes, or other devices.

[004] Many of these devices have a mechanical or electrical component located near the tip to perform some actuation of a treatment apparatus such as, for example, movement of a set of biopsy jaws or grasper, delivery of energy, actuation of a biopsy mechanism, or other actuation. Directing the tip of these devices into locations of interest, such as those identified preoperatively or intraoperatively through medical scans of the patient (such as

CT, MR, PET, SPECT, x-ray etc.) can be difficult. This is especially true if, among other things, the location of the instrument relative to a lesion or other area of interest cannot be visualized directly. If the tip of an instrument is not properly positioned, multiple problems can arise such as, for example, iatrogenic damage to tissue can be imparted, samples of tissue can be obtained that are not the intended target of the procedure, or other problems.

[005] Sometimes, the location of a target lesion or other area of interest is known on a preoperative scan but insufficient landmarks are identifiable during the actual surgical intervention to easily locate the lesion or area of interest. This is especially true if the lesion or area of interest does not appear distinctly different from surrounding tissues under readily available intraoperative imaging modalities. These intraoperative imaging modalities may include x-rays, optical examination or ultrasound. When used, the lesion, area of interest, and/or instrument may be invisible or inaccessible to the "live" (i.e., intraoperative) imaging modality, may appear in insufficient resolution, or the image of the lesion might be degraded through the presence of intervening anatomy. This may render it difficult or impossible to determine the location of the instrument relative to the lesion or area of interest using traditional intraoperative imaging. Furthermore, some imaging modalities, such as those that are based on x-rays, may impart ionizing radiation or be otherwise harmful to patient and surgeon. Even when the intraoperative imaging modalities are able to render a lesion or area of interest and instrument, the images produced can sometimes be difficult to interpret or can take excessive time to obtain. Furthermore, the imaging modalities used for the initial preoperative scans may be inappropriate or otherwise unavailable for use intraoperatively (i.e., during the actual interventional procedure).

[006] For these and other reasons, it is desirable to construct systems, devices and methods for performing interventions where an instrument's tip location can be tracked while inside the patient and a representation of the instrument can be displayed on preoperative or intra-operative scans in which

the salient anatomy is visible. It is further desirable that such systems, devices, and methods are usable with flexible instruments to perform the intervention, and that these instruments perform and function similarly to conventional instruments. It is further desirable to use such methods to track instruments that contain a therapy or tissue sampling component at the tip. It is further desirable that these operate in both soft and hard tissue.

SUMMARY OF THE INVENTION

[007] In one embodiment, the invention provides an image-guided medical instrument, which can be used in minimally invasive surgery. An example of an instrument of the invention may include an image-guided endoscopic biopsy device. Other image-guided devices/instruments may also be provided by the invention.

[008] In some embodiments, an image-guided medical instrument according to the invention may include a handle, a body member, a treatment apparatus, an operating element, a transmission element, a sensor element, and/or other elements.

[009] In one embodiment, the body member may include one or more elongated flexible elements or materials such as, for example, elongated tubing, wires, and/or other elements. In one embodiment, the body member may connect the handle to the treatment apparatus over or through the flexible elements comprising the body member. In some embodiments, the body member may also include an extended channel along its length such as, for example, the lumen of tubing, the lumen or channel of a hollow needle, or the lumen of another hollow flexible material.

[0010] In one embodiment, the body member may include or house one or more elements that transmit forces, energy, materials (e.g., solid, liquid, or gas materials) or other implements from the handle (or other part of the image-guided medical instrument) to the treatment apparatus. These elements may be referred to herein as "transmission elements." For example, transmission elements used in the invention may transmit extension/compression forces,

rotational forces, electromagnetic energy, drugs or other solid, liquid, or gas materials, or other implements. In some embodiments, the transmission elements may include elements that can transmit mechanical forces such as, for example, wires, cables, tubes, or screw mechanisms, or other elements. In other embodiments, the transmission elements may include a shape memory alloy, a fluid (e.g., liquid or gas), an optical fiber, a wave guide for sound or electromagnetic energy, or other elements. In still other embodiments, the transmission elements may include electrical cables or electrical wires.

[0011] In some embodiments, the transmission elements may be contained within the extended channel/lumen of the body member. In one embodiment, the transmission elements may move independently of the body member. In some embodiments, the body member itself may act as a transmission element.

[0012] In some embodiments, the properties of the transmission element may be tuned to provide high pushability, high torque transmission, high kink resistance, low ductility, and/or other characteristics necessary for transmitting the intended energy or material along the transmission element.

[0013] As mentioned above, the image-guided medical instrument of the invention may include a treatment apparatus. In one embodiment, the treatment apparatus may include one or more movable parts such as, for example, jaws, a snare, a moving notch, a vibrating section, a steering mechanism, or other movable parts. In some embodiments, the treatment apparatus may include one or more non-movable parts such as, for example, an optical fiber tip, an electrode tip, a suction tube, or other non-movable parts.

[0014] In one embodiment, the treatment apparatus may be connected to the transmission element. The transmission element may transmit energy and/or material from the operating element or other part of the instrument to the treatment apparatus.

[0015] In some embodiments, the treatment apparatus may be actuated when a user triggers an operating element. In some embodiments, the operating element may include a trigger or other element on the handle. For example, the

treatment apparatus may include a pair of biopsy jaws. In this example, the biopsy jaws may be opened and closed by actuating a movable trigger on the handle of the image-guided medical instrument. The movable trigger causes the transmission element to actuate the treatment apparatus. Other types operating elements may be used to actuate various types of treatment apparatuses.

[0016] The image-guided medical instrument of the invention may include at least one sensor element. In one embodiment, the sensor element may include an electromagnetic sensor element/position indicating element whose position and orientation may be tracked by an electromagnetic tracking device. Other types of tracking devices and sensor elements may be used such as, for example, inertial sensors, fiber optic position sensors, ultrasonic position sensors, global positions ("time of flight") sensors, or other devices or sensors.

[0017] In one embodiment, the sensor element may be located near the treatment apparatus along the body member. In other embodiments, the sensor element may be located elsewhere on the image-guided medical instrument. In still other embodiments, one or more sensor elements may be located near the treatment apparatus, while one or more other sensor elements may be located elsewhere on the image-guided medical instrument.

[0018] If the sensor element includes wires to receive or transmit signals, accommodation may be made to house these wires along the body member. For example, any wires necessary for the sensor element may be housed in the extended channel/lumen of the body member along with any electrical insulation, shielding, batteries, or other components.

[0019] In some embodiments, the transmission element may include a hollow tube (e.g., an "actuator tube"), in which lead-wires or other components of the sensing element can reside. Additional components may also be housed in or attached to a lumen of a hollow transmission element.

[0020] A tracking device associated with the sensor element may detect the relative position and/or orientation of the sensor element (and/or any object

rigidly attached thereto). This relative position/orientation information may be used, as described herein, to guide the image-guided medical instrument through the anatomy of a patient for the purpose of performing a procedure.

[0021] The invention also provides an image-guided surgery system that can be used with the image-guided medical instruments described herein. In particular, the device and system of the invention are particularly appropriate for the manufacture of thin elongated instruments whose distal end includes a treatment apparatus and whose proximal end includes a handle. In order to perform a procedure accurately, it is advantageous to track the proximal end of the instrument using one or more sensor elements (such as, for example, those described herein) that do not otherwise alter the function or appearance of the instrument.

[0022] These and other objects, features, and advantages of the invention will be apparent through the detailed description of the preferred embodiments and the drawings attached hereto. It is also to be understood that both the foregoing general description and the following detailed description are exemplary and not restrictive of the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] FIG. 1 illustrates an image-guided medical instrument, according to an embodiment of the invention.

[0024] FIG. 2 illustrates the end of a body member having a sensor element, according to an embodiment of the invention.

[0025] FIG. 3A illustrates an image-guided medical instrument, according to an embodiment of the invention.

[0026] FIG. 3B illustrates the tip of an image-guided medical instrument, according to an embodiment of the invention.

[0027] FIG. 4A illustrates an image-guided medical instrument, according to an embodiment of the invention.

[0028] FIG. 4B illustrates a body member of an image-guided medical instrument, according to an embodiment of the invention.

[0029] FIG. 4C illustrates the tip of an image-guided medical instrument, according to an embodiment of the invention.

[0030] FIG. 5 illustrates a system for performing a medical procedure using an image-guided medical instrument, according to an embodiment of the invention.

[0031] FIG. 6 illustrates a process for performing a medical procedure using an image-guided medical instrument, according to an embodiment of the invention.

DETAILED DESCRIPTION

[0032] In one embodiment, the invention provides an image-guided medical instrument, which can be used in minimally invasive surgery. FIG. 1 illustrates an image-guided medical instrument 100, according to an embodiment of the invention. In some embodiments, image-guided medical instrument 100 may include a body member 101, a handle 102, a treatment apparatus 103, an operating element 107, and/or other elements.

[0033] In one embodiment, body member 101 may include one or more elongated flexible elements or materials such as, for example, elongated tubing, wires, and/or other elements. For example, in one embodiment, body member 101 may include tubing 108. Body member 101 may also include coiled springs, insulating and/or protective jackets, braided elements, and/or other elements.

[0034] In one embodiment, body member 101 may include first and second ends and may connect handle 102 to treatment apparatus 103 over or through the flexible elements comprising body member 101.

[0035] Body member 101 may also include an extended channel along its length such as, for example, the lumen of tubing 108, the lumen of a hollow needle, or the lumen or channel within another hollow flexible element. The extended channel may house or contain other elements of instrument 100 and/or may act to transmit signals, forces, material, energy, and/or other implements either directly or indirectly from handle 102 or other element of instrument 100 to treatment apparatus 103.

[0036] In one embodiment, body member 101 may include or house one or more elements that transmit forces, energy, materials (e.g., solid, liquid, or gas materials) or other implements from handle 102 (or other part of instrument 100) to treatment apparatus 103. These elements may be referred to herein as "transmission elements." For example, transmission elements used in the invention may transmit extension/compression forces, rotational forces, electromagnetic energy, drugs or other solid, liquid, or gas materials, or other implements. In some embodiments, the transmission elements may include elements that can transmit mechanical forces such as, for example, wires (e.g., wire 106), cables, tubes, or screw mechanisms, or other elements. In other embodiments, the transmission elements may include a shape memory alloy, a fluid (e.g., liquid or gas), an optical fiber, a wave guide for sound or electromagnetic energy, or other elements. In still other embodiments, the transmission elements may include electrical cables or electrical wires. FIG. 1 illustrates wire 106 running though a portion of handle 102. Although not illustrated in FIG. 1, those having skill in the art will recognize that, in some embodiments, wire 106 (or other transmission element) may have first and second ends and may run from handle 102 through body member 101 to treatment apparatus 103.

[0037] In some embodiments, the transmission elements may be contained within the extended channel (e.g., a lumen of tubing 108) of body member 101. In one embodiment, the transmission elements may move independently of tubing 108 of body member 101. In some embodiments, tubing 108 of body member 101 itself may act as a transmission element and may include electrical functional or electrically activated elements (e.g., coils, piezoelectric devices, motors, thermal ablative devices, sampling vents or ports, or other electrical devices), mechanical elements (e.g., steering wires, springs, shape-set wires, tensile members, or other mechanical elements), functional elements (e.g., sliding cannulae or other functional elements), elements that change the mechanical, chemical, biological, and/or electrical characteristics of body

section 101, additional sensors (e.g., additional position indicating sensor elements, temperature sensors, pressure sensors, or other sensors), and/or other elements.

[0038] In one embodiment, treatment apparatus 103 may include one or more movable parts such as, for example, jaws, a snare, a moving notch, a vibrating section, a steering mechanism, or other movable parts. In some embodiments, treatment apparatus 103 may include one or more non-movable parts such as, for example, an optical fiber tip, an electrode tip, a suction tube, or other non-movable parts. FIG. 1 illustrates a pair of movable jaws as treatment apparatus 103. Those having ordinary skill in the art will recognize that a variety of elements including, but not limited to, the aforementioned elements may be used as treatment apparatus 103. For example, treatment apparatus 103 may include a biopsy element (e.g., biopsy jaws, a biopsy gun, a biopsy notch, endoscopic biopsy forceps, or other biopsy element), a polypectomy snare, a cytology brush, a biliary guidewire, a sphincterotome, an Endoscopic Retrograde Cholangio-Pancreatography (ERCP) catheter, a stone retrieval balloon, a stent, a lithotripsy basket, a grasper, a basket, rat-tooth forceps, alligator forceps, a sclerotherapy/injection needle, a bipolar coagulation probe, a dilation balloon, a radiofrequency ablation device, a microwave ablation device, embolic delivery device, brachytherapy device, a cryotherapy probe, and/or other treatment apparatus.

[0039] In some embodiments, treatment apparatus 103 may be actuated when a user triggers operating element 107. In some embodiments, operating element 107 may include a trigger in handle 102, which may further include an electrical switch or contact. In one embodiment, operating element 107 may include a movable part 105 that comprises all or part of operating element 107. For example, as illustrated in FIG. 1, treatment apparatus 103 includes a pair of biopsy jaws. In this example, the biopsy jaws may be opened and closed by actuating movable part 105. Movable part 105 may be operated by a thumb piece 112 of operating element 107, through which an operator's thumb may be

inserted. Finger holes 111 may also be included on handle 102, such that an operator may place one or more fingers in each finger hole 111 and slidably actuate operating element 107 with his or her thumb using thumb piece 112. This slidable actuation of operating element 107 causes wire 106 to move accordingly in body member 101, which causes the jaws of treatment apparatus 103 to open and close. Those having skill in the art will realize that the embodiment illustrated in Fig. 1 is exemplary only and that other embodiments may be used.

[0040] In one embodiment, operating element 107 may actuate an electric motor, pump, microwave generator, or other electrical or mechanical device that may be partly or fully contained in handle 102. This electrical/mechanical device may cause forces, energy, material, or other implements to be transmitted via the transmission element of body member 101 and actuate treatment apparatus 103.

[0041] In one example, operating element 107 may be purely mechanical and may actuate treatment apparatus 103 directly via transmission elements with or without the assistance of springs, pulleys, hinges, rods, cables, wires, screws or other mechanical devices. In another example, operating element 107 may be a fluidic element such as a valve and may control the passage of fluids (e.g., liquids or gasses) through transmission section 101 to operating section 103.

[0042] Image-guided medical instrument 100 may include at least one sensor element 110. In one embodiment, sensor element 110 may include an electromagnetic sensor element/position indicating element whose position and orientation may be tracked by an electromagnetic tracking device. Other types of tracking devices and sensor elements may be used such as, for example, optical tracking devices, fiber optic devices, ultrasonic devices, global positioning ("time of flight") devices, inertial sensors, or other tracking devices and sensor elements.

[0043] In one embodiment, sensor element 110 may be located near treatment section 103, along body member 101. In other embodiments, sensor element

110 may be located elsewhere on medical instrument 100. If sensor element 110 includes wires to receive or transmit signals, accommodation may be made to house these wires along body member 101. For example, the wires necessary for sensor element 110 may be housed in the extended channel of body member 101 (e.g., in the lumen of tubing 108).

[0044] As mentioned above, one embodiment of the invention includes treatment apparatus 103 that is connected to a transmission element and/or body member 101. The transmission element may, in some embodiments, transmit mechanical motion from operating element 107 to treatment apparatus 103. In these embodiments, the transmission element may include a hollow tube (e.g., an "actuator tube"), in which lead-wires from sensing element 110 can reside. Additional components may also be housed in or attached to a lumen of a hollow transmission element.

[0045] FIG. 2 illustrates a cross-section of a portion of body member 101 of image-guided medical instrument 100. Body member 101 may include tubing 108 (e.g., a jacket tube), which may be used to house a transmission element in the form of an actuator tube 201. In one embodiment, tubing 108 may include braid-reinforced or other structurally stabilized metal or plastic, or a metal spring coil that may contain additional layers or coatings depending on the use. In some embodiments, tubing 108 also may assist any actuating elements (e.g., actuator tube 201) to actuate a treatment apparatus (not illustrated in FIG. 2), thereby causing the treatment apparatus to move or operate (e.g. ablate, take tissue samples, or otherwise operate).

[0046] As mentioned above, actuator tube 201 may serve as a transmission element and thus may perform the function of transmitting forces, energy, material, or other implements from an operating element 107 (not illustrated in FIG. 2) or other element of instrument 100 to a treatment apparatus. In other embodiments, the transmission element may include a solid wire, a wire cable, or other element.

[0047] In one embodiment, actuator tube 201 (or other part of transmission section 101) may be instrumented with at least one sensor element 110. In one embodiment, sensor element 110 may be capable of providing certain parameters such as its location and/or orientation relative to a companion tracking device (or the location/orientation of any object that is rigidly attached to sensor element 110). This relative position/orientation information may be used, as described herein, to guide image-guided medical instrument 100 through the anatomy of a patient for the purpose of performing a procedure.

[0048] In one embodiment, sensor element 110 may be secured within a lumen of actuator tube 201 and may contain electrical insulation 203, electrical shielding 204, lead-wires 205, any necessary batteries, and/or other elements. In some embodiments, actuator tube 201 may include a conventional tube such as, for example, a hypodermic tube, into which sensor element 110, insulation 203, shielding 204, lead-wires 205 and/or other elements have been fixed. In another embodiment, actuator tube 201 may include a hollow multi-filar wire rope which allows for the placement of sensor element 110 and/or any elements within the core of the wire rope.

[0049] In one embodiment, lead-wires 205 (signal carrying wires) may be threaded back through the lumen/hollow core of actuator tube 201 to the handle (e.g., handle 102) of instrument 100. In an alternate embodiment, lead-wires 205 may be incorporated into the wall of a tube (e.g., tubing 108, actuator tube 201, or other tube) using, for example, the conductor embedded Polyimide tubing manufactured by the Phelps Dodge Company. In one embodiment, lead-wires 205 may exit medical instrument 100 at its handle (e.g., see item 104 of FIG. 1).

[0050] The properties of actuator tube 201 or other transmission element may be tuned to provide high pushability, high torque transmission, high kink resistance, low ductility, and/or other characteristics necessary depending on the intended force, energy, material or other implement to be transmitted.

[0051] In some embodiments, sensor element 110 may be connected to external devices such as, for example, sensor element 110's companion tracking device, one or more computer-implemented systems, a control unit, or other devices. Sensor element 110 may be connected to these devices using either a wired or wireless configuration. In some embodiments, a wireless tracking device/sensor element apparatus may be powered externally or by using batteries.

[0052] In other embodiments, lead-wires 205 may be incorporated into or attached to another part of body member 101. For example, a solid actuator wire may be used in place of or in addition to actuator tube 201. In this example, a conductor embedded tube or lead-wires 205 themselves can be overlaid over top of an actuator wire. In still another embodiment, a notch carved along the length of the actuator wire can be used to house lead-wires 205.

[0053] In one embodiment, sensor element 110 may be bonded to an actuation cable and lead-wires 205 may be connected to the cable strands or wound with them, and signals conducted down the actuation cable. In yet another embodiment, a hollow sensor element 110 may be used and an actuation wire may pass through the center of the hollow sensor element 110. In this embodiment, lead-wires 205 may run alongside the actuation wire or can be routed through the center of a hollow actuation wire. In this case, hollow sensor element 110 may be bonded to an external jacket (e.g., the jacket tube comprising tubing 108), and an actuation wire may be freely slidable through the center of hollow sensor element 110.

[0054] In yet another embodiment, a force transmission element other than actuator tube 201 may include a solid wire that has been machined to contain a groove along its length for lead wires 205 to run, and a space integrated into the wire near the distal end for sensor element 110.

[0055] Referring back to FIG. 2, at the distal tip of actuator tube 201, additional components such as, for example, items 208 and/or 209 may be welded or

otherwise attached to, or formed from, actuator tube 201 or other transmission element. Items 208 and/or 209 may enable a hollow actuator tube 201 to be efficiently adapted for attachment to a treatment apparatus without having to significantly alter existing or pre-manufactured treatment apparatus components (e.g., standard biopsy jaws or other standard or pre-manufactured components).

[0056] FIGS. 3A and 3B illustrate an image-guided medical instrument 300 according to an embodiment of the invention. Instrument 300 illustrates a biopsy device. However, those of skill in the art will realize that medical instruments having other functions may be similarly utilized as image guided medical instrument 300. Image-guided medical instrument 300 includes a handle 301. In one embodiment, handle 301 may include an operating element 302, which may enable actuation of a treatment apparatus 306.

[0057] Image-guided medical instrument 300 also includes an elongated body member 303. In one embodiment, body member 303 may include a hollow cannula 315. In some embodiments, hollow cannula 315 may serve as a protective jacket tube and/or may enable functionality of treatment apparatus 306, as described below. FIG. 3B illustrates a cross-section of a portion body member 303 that is attached to treatment apparatus 306. In one embodiment, body member 303 may include a transmission element 304. Transmission element 304 may include a hollow tube that is freely slideable within the jacket tube provided by hollow cannula 315.

[0058] A sensor element 305 may be fixed within transmission element 304 near its end or may be housed in another part of instrument 300. Lead-wires 309 may extend from sensor element 305 back through transmission element 304 to handle 301 where lead-wires 309 can exit at a location 310 to an external cable 311 and ultimately to a device 312 that can process the signal from sensor element 305 (e.g., a tracking device, a computer-implemented processing system, and/or a control unit).

[0059] In one embodiment, instrument 300 may also include a treatment apparatus 306. Treatment apparatus 306 may include a section of wire or other material that is welded or otherwise fixed to transmission element 304. Treatment apparatus 306 may be manufactured in the manner of existing biopsy devices so that it includes a notched section 307 and a point 308. Point 308 may be beveled or come to a sharp point.

[0060] The actuation of device 300 may cause hollow cannula 303 to slide forward (e.g., to the right as illustrated in FIGS. 3A and 3B) over notched section 307 of treatment apparatus 306, trapping a sample of tissue in the notch of notched section 307. As such, in this embodiment, transmission element 304, does not directly transmit forces that actuate treatment apparatus 306, as much as it serves as a guide/support for hollow cannula 315.

[0061] FIGS. 4A, 4B and 4C illustrate an image-guided medical instrument 400 according to an embodiment of the invention. As illustrated, instrument 400 is an endoscopic biopsy gasper. However, instrument 400 is exemplary only. Those having skill in the art will recognize that instruments having different treatment apparatuses may be used.

[0062] As illustrated, instrument 400 includes a handle 401, a body member 403, and a treatment apparatus 407. Handle 401 includes an operating element 402 that enables actuation of treatment apparatus 407.

[0063] Body member 403 may include flexible hollow tube 411, which may serve as a protective jacket tube. Body member 403 may also include a transmission element 404. Transmission element 404 may include a flexible hollow tube that is housed within and is freely slideable within jacket tube 411.

[0064] A sensor element 405 may be fixed within the lumen of transmission element 404 near its distal end. A tip section 406 of wire or other material may be welded or otherwise fixed to transmission element 404. Tip section 406 may be manufactured so that it can connect an otherwise standardized treatment section 407 (in this embodiment, a pair of biopsy jaws usable with traditional

medical instruments) to transmission section 403, thereby saving the effort of redesigning special jaws.

[0065] Lead-wires 408 may extend from sensor element 405 back through transmission element 404 or other part of transmission section 403, to handle 401. Lead-wires 408 then exit handle 401 to an external cable 409 and may ultimately connect to a device 410 that can process the signal from sensor element 405 (e.g., a tracking device or computer-implemented processing device).

[0066] FIG. 4C illustrates sensor element 405 and treatment apparatus 407 in detail. As illustrated, jacket tube 411 is connected to the hinge mechanism 420 via tip portion 406. In the region at the distal end of sensor element 405, hollow force transmission element 404 is attached to a standard mechanism for treatment apparatus 407 (in this embodiment, the pair of biopsy jaws).

[0067] FIG. 5 illustrates an image-guided surgery system 500 according to an embodiment of the invention that can be used with the image-guided medical instruments provided by the invention (e.g., instruments, 100, 300, 400, or other instruments). System 500 may include a memory device 501, a processing unit 503, a display device 505, a position sensing device 507, an image-guided medical instrument 509, and/or other elements.

[0068] In one embodiment, system 500 may include memory device 501. Memory device 501 may include a hard-drive, flash memory, or other computer-implemented memory that receives and stores image data obtained from an imaging modality such as, for example, an x-ray device, a magnetic resonance imaging (MRI) device, a positron emission tomography (PET) device, a fluoroscopic device, and ultrasound device, or other imaging modality. Memory device 500 may also receive and store position and/or orientation data related to a sensor element and may store other data for use with the systems and methods of the invention.

[0069] In one embodiment, system 500 may also include processing unit 503. Processing unit may include one or more computer-implemented

microprocessors and/or computer systems including one or more microprocessors. Processing unit 503 may processes and/or manipulate image data related to a patient's anatomy, position and/or orientation data regarding a sensor element, and/or other data for use in image guided surgery and the systems and methods of the invention.

[0070] System 500 may also include display device 505. Display device 500 may include a computer monitor (e.g., cathode ray tube, LCD screen, or other monitor) that produces one or more images illustrating image data, position data, combinations thereof, or other data to a user (e.g., a surgeon).

[0071] System 500 may also include a tracking device 507 that can detect the location and orientation of a sensor element/position indicating element (e.g., sensor element 110, 305, 405) in image-guided medical instrument 509. In one embodiment, tracking device 507 may include an electromagnetic tracking device that can detect the position and/or orientation of one or more electromagnetic sensor elements/position indicating elements. Other types of tracking devices and sensor elements may be used such as, for example, optical tracking devices/sensor elements, fiber optic devices, ultrasonic devices, global positioning ("time of flight") devices, inertial sensor devices, or other tracking devices and sensor elements.

[0072] In some embodiments, system 500 may also include one or more software modules enabling the features and functions of the invention. Those having skill in the art will appreciate that the invention described herein may work with various system configurations. Accordingly, more or less of the aforementioned system components may be used and/or combined in various embodiments. It should also be understood that software modules used to accomplish the functionalities described herein may be maintained on one or more of the components of system recited herein, as necessary, including those within individual medical tools or devices. In other embodiments, as would be appreciated, the functionalities described herein may be implemented in various

combinations of hardware and/or firmware, in addition to, or instead of, software.

[0073] FIG. 6 illustrates a process 600 for using an image guided medical instrument (e.g., instrument 100, 300, 400) with an image-guided surgery system (e.g., system 500) for performing image guided surgery or other image-guided procedure/intervention. Process 600 includes an operation 601, wherein images of a patient's anatomy obtained using an imaging modality are registered to a patient space according to one or more methods known in the art. For information regarding registration, image-guided surgery, or other information related to the invention, see U.S. Patent Application No. 11/059,336 (U.S. Patent Publication No. 2005/0182319), entitled "Method and Apparatus for Registration, Verification, and Referencing of Internal Organs," which is hereby incorporated by reference herein in its entirety.

[0074] In an operation 603, a graphic representation of part or all of the image-guided medical instrument is generated and superimposed on one or more images (e.g., preoperative images) of the patient anatomy. In an operation 605, these superimposed images are displayed on the display device. In some embodiments, the position of the sensor element may be extrapolated to the tip of the image-guided medical instrument, to the center of the treatment apparatus (e.g., to the middle of the jaws) or some other suitable location that is convenient in the context of the intervention (e.g., the location most relevant to guiding the treatment apparatus to a location of interest) using the known relationship between the treatment apparatus (or other location) and the sensor element. In an operation 607, the image-guided medical instrument can be navigated to a treatment location, sampling location, or location of interest in the anatomy of a patient using the superimposed representation of the instrument on the one or more images of the patient's anatomy.

[0075] In an operation 609, when the display device shows that the treatment apparatus of the medical instrument is in a treatment or sampling location, an operating element (e.g., operating elements 107, 302, 402) can be actuated to

actuate a treatment apparatus (e.g., treatment apparatuses 103, 306, 407) via a transmission element (e.g., transmission elements 201, 304, 404) and a sample may be taken or therapy may be delivered.

[0076] Other embodiments, uses and advantages of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. The specification should be considered exemplary only, and the scope of the invention is accordingly intended to be limited only by the following claims.

Claims

What is claimed is:

1. An image-guided medical instrument that utilizes a tracking device to track a location of at least a portion of the instrument on at least one image of an anatomy, the image-guided medical instrument comprising:

a handle that includes an operating element;

an elongated flexible body member having first and second ends, wherein the first end of the body member is connected to the handle, and wherein the body member includes a lumen;

a transmission element having first and second ends, wherein the first end of the transmission element is connected to the operating element, and wherein the transmission element is located in the lumen of the body member;

a treatment apparatus connected to the second end of the body member and the second end of the transmission element, wherein actuation of the operating element actuates the treatment apparatus via the transmission element; and

at least one sensor element located within the lumen of the body member, that is utilized by the tracking device to obtain position information regarding a position of the at least one sensor element, wherein the location of the treatment apparatus on the at least one image of the anatomy is determined using the position information of the at least one sensor element.

2. The image-guided medical instrument of claim 1, wherein the body member comprises a hollow tube.

3. The image-guided medical instrument of claim 1, wherein the body member comprises a torqued cable bundle.

4. The image-guided medical instrument of claim 1, wherein the body member comprises a hollow helical spring winding.

5. The image-guided medical instrument of claim 1, wherein the transmission element comprises a wire, and wherein the treatment apparatus is actuated when force is transmitted along the transmission element.

6. The image-guided medical instrument of claim 1, wherein the transmission element comprises a wire having a lumen, wherein the at least one sensor element includes electrical connections residing in the lumen of the transmission element.

7. The image-guided medical instrument of claim 1, wherein the transmission element includes one or more electrical conductors that serve as signal pathways for the at least one sensor element.

8. The image-guided instrument of claim 1, wherein the transmission element includes one or more electrical conductors provide electrical energy to the treatment apparatus.

9. The image-guided instrument of claim 1, wherein the transmission element includes one of a waveguide that transmits microwave energy to the treatment apparatus or an optical fiber that transmits optical energy to the treatment apparatus.

10. The image-guided medical instrument of claim 1, wherein the position information includes information regarding the orientation of the at least one sensor element.

11. The image-guided medical instrument of claim 1, wherein the at least one sensor element is located at the second end of the body member adjacent to the treatment apparatus.

12. The image-guided medical instrument of claim 1, wherein the treatment apparatus comprises a biopsy device.

13. The image-guided medical instrument of claim 1, wherein the treatment apparatus comprises one of a biopsy element, a biopsy notch, endoscopic biopsy forceps, a polypectomy snare, a cytology brush, a biliary guidewire, a sphincterotome, an Endoscopic Retrograde Cholangio-Pancreatography (ERCP) catheter, a stone retrieval balloon, a stent, a lithotripsy basket, a grasper, a basket, rat-tooth forceps, alligator forceps, a sclerotherapy/injection needle, a bipolar coagulation probe, a dilation balloon, a

radiofrequency ablation device, a microwave ablation device, embolic delivery device, brachytherapy device, or a cryotherapy probe.

14. The image-guided medical instrument of claim 1, wherein the tracking device includes an electromagnetic tracking device and the sensor element includes an electromagnetic position sensor.

15. The image-guided medical instrument of claim 1, wherein sensor element includes one of an inertial sensor, an ultrasonic position sensor, or a fiber optic position sensor.

16. A computer-implemented system for performing a procedure on a location of interest within a portion of an anatomy of a patient using at least one image of the anatomy of the patient, the system comprising:

a data storage device that receives and stores the at least one image of the anatomy of the patient;

an image-guided medical instrument that includes an operating element, a transmission element, a treatment apparatus and at least one sensor element, wherein the transmission element connects the operating element and the treatment apparatus, and wherein actuation of the operating element serves to actuate the treatment apparatus via the transmission element;

a tracking device that obtains position information regarding a position of the at least one sensor element;

a display device; and

a computer-implemented processor that utilizes the position information to display a location of the treatment apparatus on the at least one image of the anatomy of the patient on the display device, wherein the displayed location of the treatment member is used to guide the treatment apparatus to the location of interest and perform the procedure, wherein the procedure is performed upon actuation of the treatment apparatus.

17. The system of claim 16, wherein the processor displays the location of the treatment apparatus on the at least one image of the anatomy of

the patient by registering the position information to the at least one image of the anatomy of the patient.

18. The system of claim 16, wherein the tracking device includes an electromagnetic tracking device and the sensor element includes an electromagnetic position sensor.

19. The system of claim 16, wherein the procedure is a biopsy and the treatment member is a biopsy device.

20. A method for performing a procedure on a location of interest within a portion of an anatomy of a patient using at least one image of the anatomy of the patient, a tracking device, and an image-guided medical instrument, wherein the image-guided medical instrument includes an operating element, a transmission element, a treatment apparatus, and at least one sensor element that is trackable by the tracking device, the method comprising:

receiving the at least one image of the anatomy of the patient;

registering position information regarding the position of the at least one sensor element to the at least one image of the anatomy of the patient;

displaying the location of the treatment apparatus on at least one image of the anatomy of the patient;

navigating the treatment apparatus to the location of interest using the displayed location of the treatment member; and

performing the procedure on the location of interest by actuating the operating element which actuates the treatment apparatus via the transmission element.

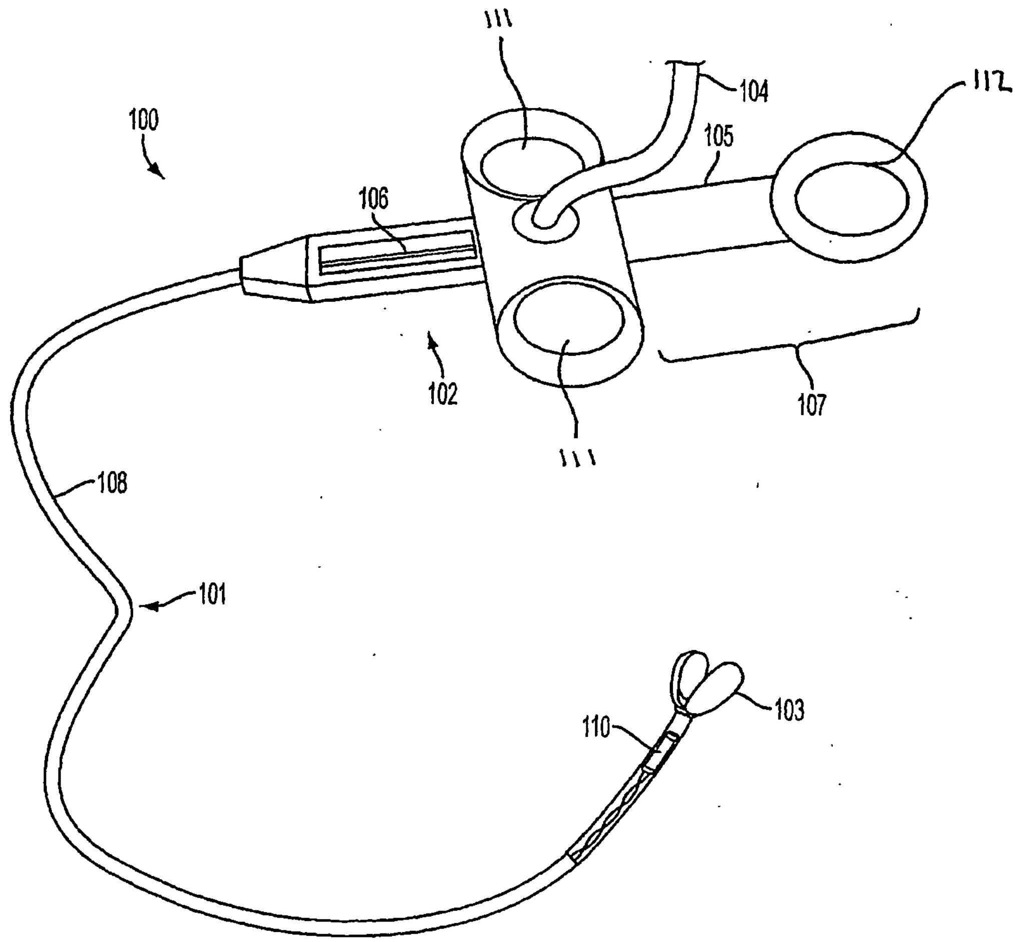


FIG. 1

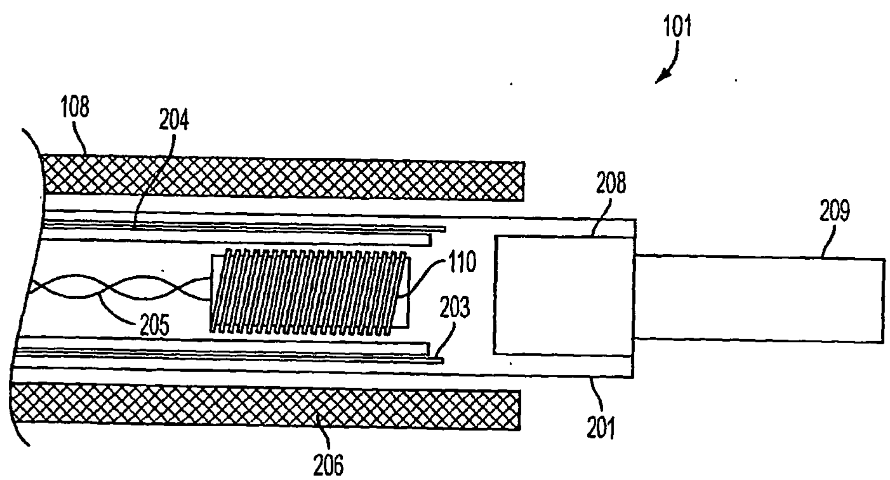


FIG. 2

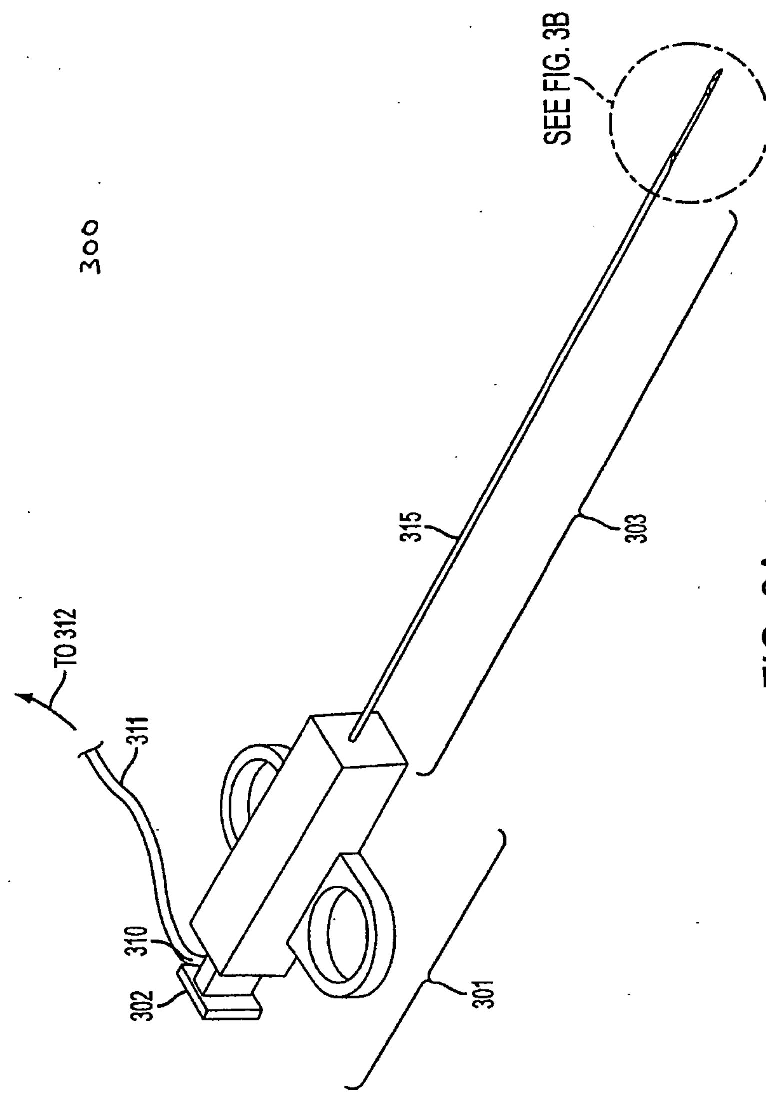


FIG. 3A

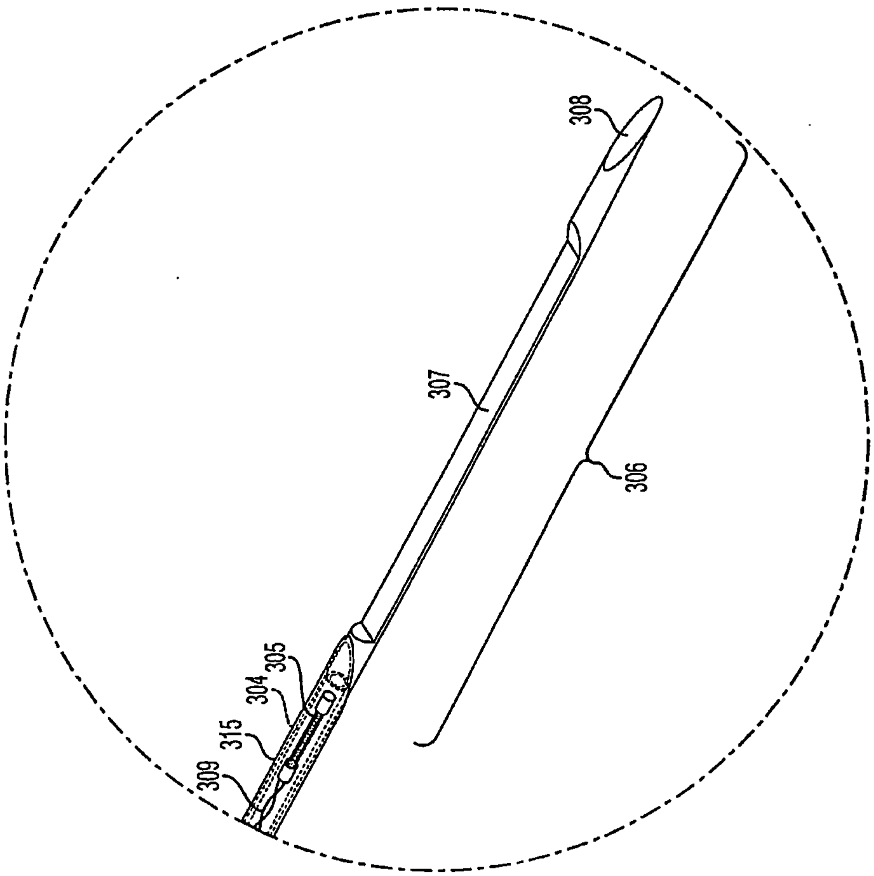
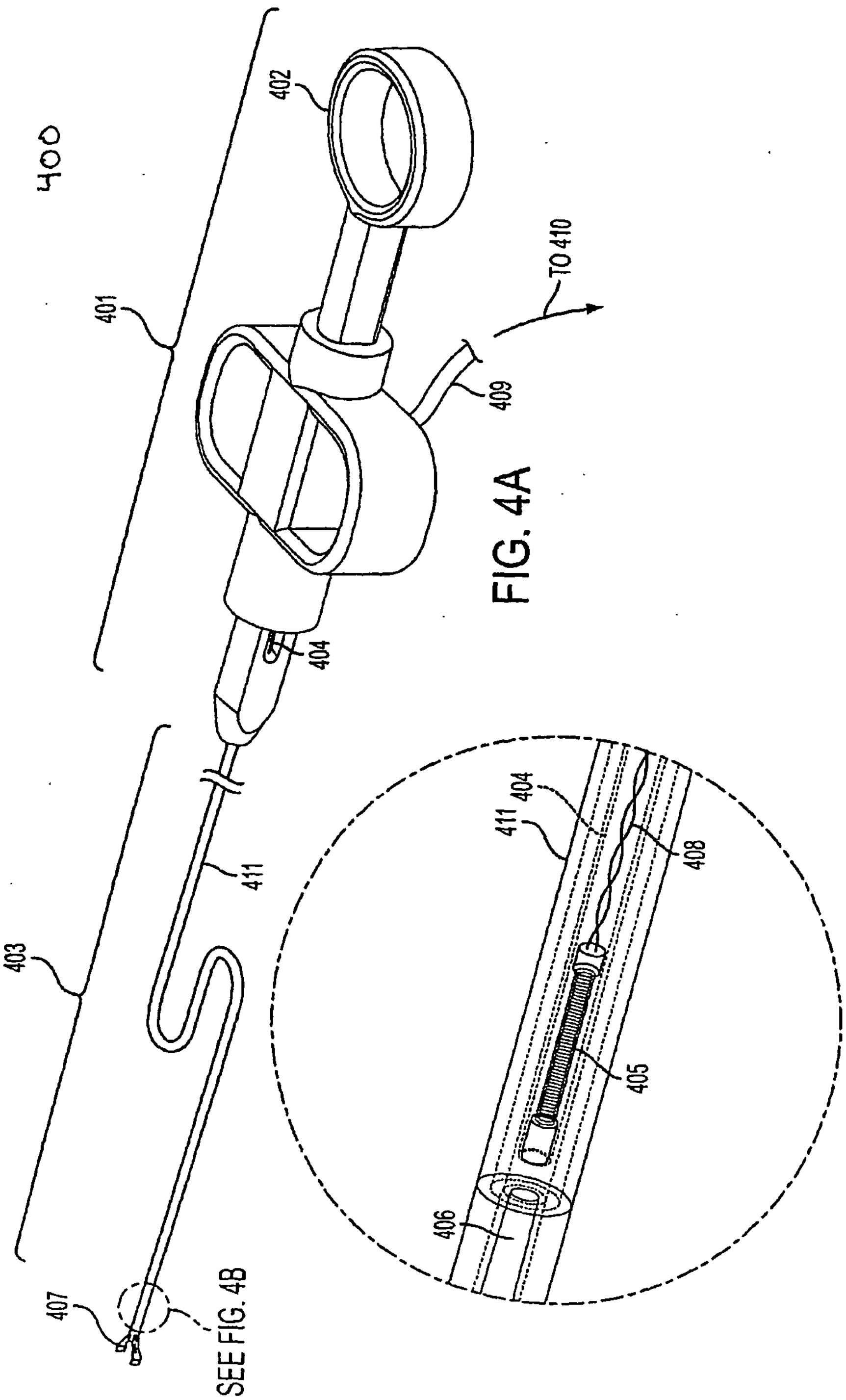


FIG. 3B


400
402
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TO 410
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404
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407
SEE FIG. 4B
411
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408
405
406

FIG. 4A

FIG. 4B

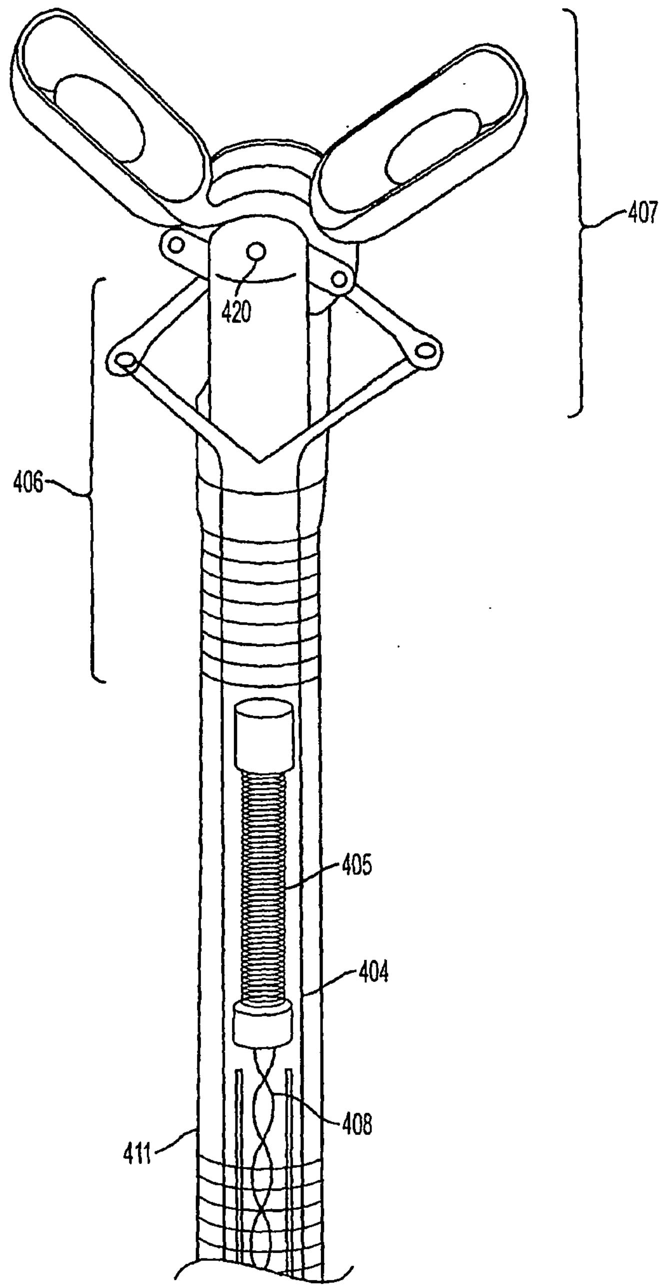

FIG. 4C

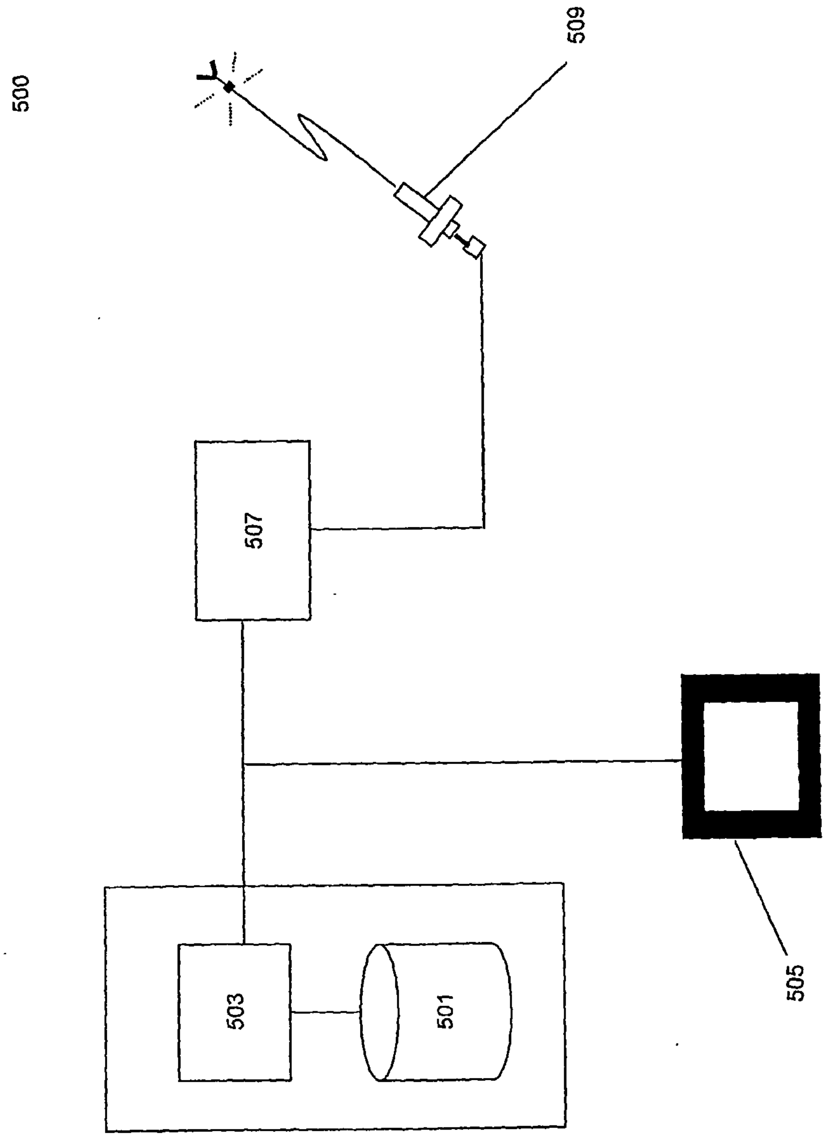

FIG. 5

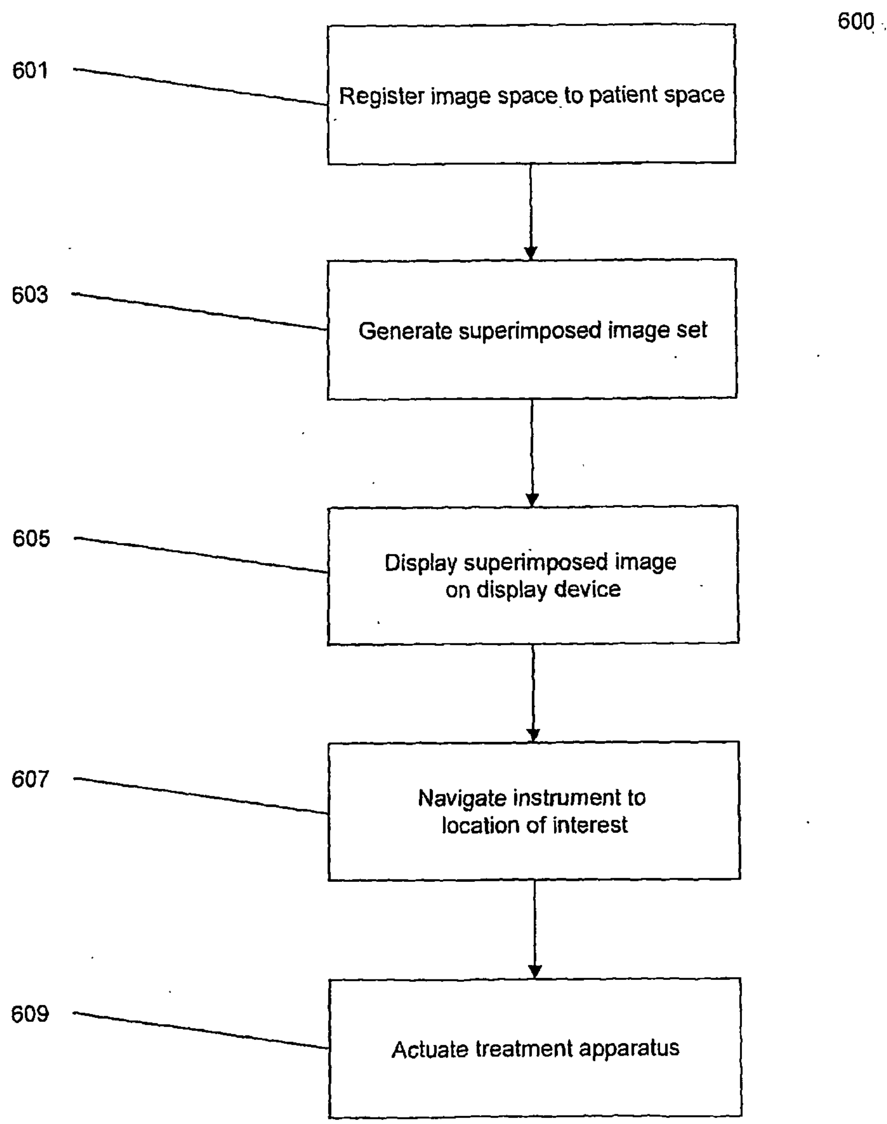
600
601
Register image space to patient space
603
Generate superimposed image set
605
Display superimposed image on display device
607
Navigate instrument to location of interest
609
Actuate treatment apparatus

FIG. 6